

Claims

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- 5 1. A medical device for dispensing drugs for the
selective treatment of specific diseased tissue
sections or organ parts, characterized in that
lipophilic drugs largely insoluble by water and
binding to any of the tissue constituents adhere to
10 the surface of devices that contact the diseased
tissue under pressure for at least a short period of
time as a dry coating without a matrix or with a
solid matrix in such a way that said drugs detach
immediately upon tissue contact, the carrier of the
15 active agent being at least a balloon catheter (12),
and in that said balloon catheter (12) comprises an
apparatus (24) that protrudes from its balloon (14)
or sits on the surface of the balloon (14) for
slitting stenoses at least in the area of the
20 diseased tissue sections or organ parts.
2. The device according to claim 1, characterized in
that the apparatus (24) for slitting stenoses
consists of at least one wire-like device (16) that
25 is arranged in parallel to the longitudinal axis of
the balloon (14).
3. The device according to claim 2, characterized in
that the apparatus (24) is composed of at least two
30 wire-like devices (16) and forms a grid-like design,
the longitudinal axis of which is arranged in
parallel or axially parallel to the longitudinal axis
of the balloon (14).

4. The device according to claims 2 or 3, characterized in that the wire-like device (16) consists of metal, a metal alloy, or of plastic.
- 5 5. The device according to claim 4 wherein the metal alloy is a shape memory alloy.
6. The device according to claim 1, characterized in that the apparatus (24) for slitting stenoses
10 consists of at least one blade-like device.
7. The device according to claim 1, characterized in that the apparatus (24) for slitting stenoses consists of at least one projection that protrudes
15 from the balloon (14) or sits on the surface of the balloon (14).
8. The device according to claims 6 or 7, characterized in that the blade-like device or projection consists
20 of metal, a metal alloy, or of plastic.
9. The device according to any one of the preceding claims, characterized in that the balloon catheter (12) is connected to guiding catheters and/or parts
25 thereof, needles, and guide wires.
10. The device according to any one of the preceding claims, characterized in that balloons with preformed longitudinal folds are used for coating with the
30 drug.
11. The device according to one of claims 1 through 9, characterized in that the balloons have smooth
35 surfaces.

12. The apparatus according to any one of claims 1 through 10, characterized in that balloons coated by immersion in fully folded condition in a low-viscosity solution of the active agent are used.
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13. The apparatus according to any one of claims 1 through 12, characterized in that only the area covered by the folds is covered with the drug that was dried after application.
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14. The apparatus according to claim 1, characterized in that the lipophilic drugs are inhibitors of cell proliferation or inflammatory processes, or antioxidants.
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15. The apparatus according to claim 14, characterized in that the drugs used are Paclitaxel and other taxanes, Rapamycin and related substances, tacrolimus and related substances, corticoids, sexual hormones and related substances, statins, epothilones, probucol, prostacyclins, or inducers of angiogenesis.
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16. The apparatus according to claim 14 or 15, characterized in that the lipophilic drugs are present as dry solids or oils on the surface of the respective product.
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17. The apparatus according to claim 16, characterized in that the effective dose of the drug includes amorphous structures with particle sizes ranging from < 0.1 μm to 5 μm that dissolve fast despite the poor water solubility of the active ingredients.
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18. The apparatus according to claim 1, characterized in that the lipophilic drugs are embedded in a readily water-soluble matrix substance to achieve good
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adhesion to the apparatus and improve absorption by the tissue.

- 5 19. The apparatus according to claim 18, characterized in that said matrix substance consists of a low-molecular hydrophilic substance with a molecular weight < 5000 D.
- 10 20. The device according to claim 19, characterized in that the matrix substances are selected from the group consisting of contrast agents and dyes used in vivo for diagnostic procedures, sugars and related substances, in particular sugar alcohols, biocompatible organic and inorganic salts, in 15 particular benzoates, as well as salts and other derivatives of salicylic acid.
- 20 21. The device according to claim 20, characterized in that the matrix substances are one or several iodized X-ray contrast agents and/or paramagnetic chelates.
- 25 22. The apparatus according to claim 1, characterized in that the lipophilic drugs are absorbed to particles, or applied to the surface of the device with a low-molecular matrix.
- 30 23. The apparatus according to claim 1, characterized in that the surface is additionally coated with substances that influence specific properties such as the gliding quality of the device, or that prevent blood coagulation.
- 35 24. A method for producing the device according to claims 1 through 23, characterized in that the lipophilic drugs and adjuvants in a solution, suspension or emulsion medium are applied using an immersion,

spreading, or spraying process or a volume gage while substances that adhere loosely to the surface are removed.

- 5 25. The method according to claim 24, characterized in that the coating process is carried out repeatedly for repeatable increase of the active agent content with the same or different solution, suspension, or emulsion media and/or adjuvants.
- 10 26. The method according to claim 25 wherein ethanol, isopropanol, ethyl acetate, diethyl ether, acetone, water or mixtures thereof are used as solution, suspension, and emulsion media.
- 15 27. The method according to one of claims 24 through 26 wherein balloons folded ready for use that are coated prior to or after sterilization are used as active agent carriers.
- 20 28. The method according to claim 27, characterized in that the balloons are coated with the respective lipophilic drugs in unfolded condition and that the balloons are folded with a tool wetted with
- 25 particularly lubricating, optionally biocompatible, gliding agents.
- 30 29. The method according to claim 24, characterized in that the completely coated device is sterilized using ethylene oxide.
- 35 30. Use of the medical devices designed according to claims 1 through 29 for producing a means for generating high local concentrations of drugs.

31. Use of the medical devices designed according to claims 1 through 29 for producing a means for creating open passages in the body.